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ATTORNEY DOCKET NO. CONFIRMATION NO.

APPLICATION NO. 10/662,165 FILING DATE 09/03/2003 FIRST NAMED INVENTOR

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22115

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12/16/2004

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC

EXAMINER
HUANG, EVELYN MEI

1548

INTELLECTUAL PROPERTY DEPARTMENT

475 HALF DAY ROAD

SUITE 500

LINCOLNSHIRE, IL 60069

ART UNIT PAPER NUMBER

1625

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary		Application No.	Applicant(s)	
		10/662,165	YASUMA ET AL.	
		Examiner	Art Unit	
		Evelyn Huang	1625	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1)	Responsive to communication(s) filed on			
2a) <u></u>	This action is <b>FINAL</b> . 2b) ☐ This	action is non-final.		
3)□	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims				
5) 6) 7)	4)  Claim(s) 1-19 and 21-37 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5)  Claim(s) is/are allowed.  6)  Claim(s) is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) 1-19, 21-37 are subject to restriction and/or election requirement.			
Application Papers				
9)☐ The specification is objected to by the Examiner.				
10)	10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)				
2)	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date	4)		

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## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 20, and claims 1-19, 23-25, 37 in part, drawn to a compound of formula I wherein ring B is benzo, the composition and process of making.

Group II, claim(s) 21, and claims 1-19, 23-25, 37 in part drawn to a compound of formula I wherein ring B is thiopyrano, the composition and process of making.

Group III, claim(s) 1-18, 23-25, 37 in part, drawn to a compound of formula I not included in Group I or II, the composition and process of making. If this group were elected, a species election would be required, and further restriction would also be required.

Group IV, claim(s) 25-35, drawn to multiple methods of use. If this group were elected, election of a single compound and a specific disease would be required, and further restriction would also be required.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the benzothienopyridine of Group I, the thiopyranopyridine of Group II, and the compound of Group III wherein Y is 5 or 7-8-membered ring optionally containing undefined number of oxygen or sulfur atoms would not have been of sufficient similarity to allow for the Markush grouping exhibiting utility, absent some teaching of equivalence in the prior art.

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Under PCT Rule 1.31 and 13.2 and 37 CFR 1.475, an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to one of the following combinations of categories:

- a. A product and a process especially adapted for the manufacture of the said product; or
- b. A product and a process of use of said product; or
- c. A product, a process specially adapted for the manufacture of the said product, and a use of the said product.

This application contains claims to more than one of the combinations of categories of invention set forth above since it contains multiple processes of use as described in Group IV invention.

Applicant is requested to select a process of use from Group IV to be examined with the Group I invention.

- 3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Evelyn Huang

**Primary Examiner** 

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